

### Response

Claims 1-27 and 48-51 are currently pending. In view of the remarks below, reconsideration of the rejections of the Office Action is respectfully requested.

#### Claim Rejections Under 35 U.S.C. §102(b)

The Examiner has rejected claims 1-11, 13-16, 18-21, 27 and 48-51 under 35 U.S.C. 102(e) as allegedly anticipated by Rudakov et al. (U.S. Patent No. 6,451,050). The Examiner asserts that Rudakov discloses a composite device for delivery of bioactive agents including the limitations of the claims. Applicant respectfully traverses this rejection, noting that Rudakov does not disclose or suggest a composite device in which there are two polymeric layers bonded to each other. Instead, as will be discussed below, Rudakov discloses a device in which the two layers are bonded to an intermediate structural member.

Rudakov discloses a stent graft incorporating two sleeves wherein a "plurality of separate expandable metallic rings are axially disposed along the length of" the sleeves. (Col. 1, lines 54-56). In between the rings are "bands of a flexible material compatible with the material of the inner and outer sleeves" which are disposed "between the inner and outer sleeves." (Col. 1, lines 65-67).

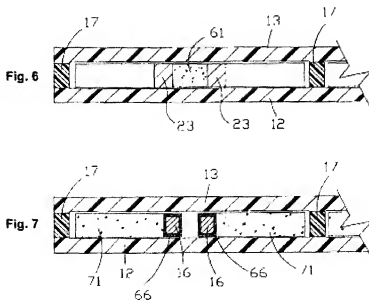
Contrary to the assertion of the Examiner, the two sleeves in Rudakov are not bonded to each other, but instead are bonded to the rings and the bands. To allow for the bonding to the sleeve, Rudakov states that the bands are preferably "formed of a material which can fuse to the inner and outer sleeves." (Col. 2, lines 62-64). Rudakov explicitly states that

The inner and outer sleeves 12 and 13 can be bonded together by **the use of the flexible bands 17** by applying heat to the outer sleeve 13 at appropriate circumferential locations. Alternatively, the entire multi-layer assembly can be placed in an oven ... to cause **bonding of the bands to the inner surface of the outer sleeve 13 and the outer surface of the inner sleeve 12.**

(Col. 3, lines 7-15) (emphasis added).

As disclosed, the device of Rudakov is designed to provide a composite device where the outer and inner sleeves are bonded to the bands, and not to each other. Rudakov states that the bands provided between the rings serve "as circumferential lines of attachment between the inner and outer sleeves." (Col. 5, lines 60-61). The sleeves of the Rudakov device are only attached to the intermediate member, and not attached to each other.

Reference to the Figures of Rudakov confirms that the disclosed device has two sleeve layers that are only attached to the intermediate member, and are not bonded to each other. The unbonded sleeve layers can be seen, for example, in Figures 6 and 7, depicted below, which show a close-up "cross-sectional view" of the Rudakov graft. In particular, Figure 7 shows a cross-sectional view of the stent-graft "having drug or agent delivery capabilities." (Col. 1, lines 45-49).



As can be seen in the above Figures, there are two sleeve layers (12 and 13), which are kept separate by the intermediate layer. The Rudakov device incorporates flexible bands (17),

rings (16), and convolutions of the ring (23), which are bonded to the sleeve layers. With particular reference to Figure 6, a tablet (61) may be provided, which serves to separate the sleeves. Additionally, with particular reference to Figure 7, a dissolvable polymer (71) is located between the sleeve layers. It is clearly demonstrated in the Figures that Rudakov intended to keep the sleeve layers separate. There is no disclosure, explicit or inherent, in Rudakov that the sleeve layers are bonded to each other.

There is absolutely no disclosure or suggestion to bond or join the two sleeve layers directly to each other, let alone to bond or join the two sleeve layers "through the openings" of the stent, as is claimed in the present application. As mentioned above, it is clear that the sleeve layers of Rudakov are bonded to the intermediate layer, which includes the rings, the bands, and the convolutions of the ring.

The present invention, unlike the device in Rudakov, includes two polymeric layers that are directly bonded to each other. The claims of the present invention require that there be a first and second polymeric layer, and an intermediate structure member between the layers. The intermediate structure includes solid segments and openings therebetween. The claims require that the first liner be bonded or joined to the second liner through these openings. This limitation is not disclosed by Rudakov, either explicitly or inherently, and thus claims 1-11, 13-16, 18-21, 27 and 48-51 are deemed to be patentably distinct over Rudakov.

Since Rudakov fails to disclose that the two sleeves are attached directly to each other, it is respectfully requested that the rejection over Rudakov be withdrawn.

**Claim Rejections Under 35 U.S.C. §103 (a)**

**Claim 12**

The Examiner has rejected claim 12 under 35 U.S.C. 103(a) as allegedly obvious over Rudakov in view of Helmus et al. (U.S. Publication No. 2002/0032477). The Examiner relies upon the Helmus reference for its disclosure with respect to using microparticles in a matrix for releasing bioactive agents.

Claim 12 depends on claim 1. As set forth above, claim 1 is patentably distinct over the primary reference. The Helmus reference fails to fill the deficiencies of the primary reference with respect to claim 1. Therefore, as a dependent claim, claim 12 is similarly patentable. It is respectfully submitted that claim 12 is patentable over Rudakov and Helmus, each taken alone or in combination.

**Claim 17**

The Examiner has also rejected claim 17 under 35 U.S.C. 103(a) as allegedly obvious over Rudakov in view of Buirge et al. (U.S. Patent No. 5,693,085). The Examiner relies upon the Buirge reference for its disclosure with respect to using a natural polymer, specifically collagen, to comprise the polymeric liners.

Claim 17 depends on claim 1. As set forth above, claim 1 is patentably distinct over the primary reference. The Buirge reference fails to fill the deficiencies of the primary reference with respect to claim 1. Therefore, as a dependent claim, claim 17 is similarly patentable. It is respectfully submitted that claim 17 is patentable over Rudakov and Buirge, each taken alone or in combination.

Claims 22-26

The Examiner has also rejected claims 22-26 under 35 U.S.C. 103(a) as allegedly obvious over Rudakov in view of Lentz (U.S. Patent No. 6,428,571). The Examiner relies upon the Lentz reference for its disclosure with respect to incorporating two separate liners having different porosities. Thus, the Examiner asserts that it would have been obvious to incorporate two liners, one with an internodal distance less than 40 microns, and the second having an internodal distance of greater than 40 microns.

Claims 22-26 depend on claim 1. As set forth above, claim 1 is patentably distinct over the primary reference. The Lentz reference fails to fill the deficiencies of the primary reference with respect to claim 1. Therefore, as a dependent claim, claims 22-26 are similarly patentable. It is respectfully submitted that claims 22-26 are patentable over Rudakov and Lentz, each taken alone or in combination.

Summary

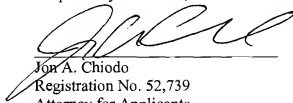
Applicant has responded in full to the present final Office Action. It is believed that all of the claims of the present invention are patentable over the cited references, either alone or in combination. Favorable action thereon is respectfully solicited.

The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication, or credit any overpayment, to Deposit Account No. 08-2461. Such authorization includes authorization to charge fees for extensions of time, if any, under 37 C.F.R. § 1.17 and also should be treated as a constructive petition for an extension of time in this reply or any future reply pursuant to 37 C.F.R. § 1.136.

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Should the Examiner have any questions or comments concerning this Response, the Examiner is respectfully invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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